



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2017-F-5528]

Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide as a Carrier for Flavors

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of silicon dioxide as a carrier for flavors for use in animal feed. This action is in response to a food additive petition filed by Idemitsu Kosan, Cp. Ltd.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section V of this document for information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-F-5528 for "Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide as a Carrier for Flavors for Use in Animal Feed." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-224), Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the *Federal Register* of September 25, 2017 (82 FR 44542), FDA announced that we had filed a food additive petition (animal use) (FAP 2304) submitted by Idemitsu Kosan, Cp. Ltd., Agri-Bio Business Dept., 1-1 Marunouchi 3-Chome, Chiyoda-Ku, Tokyo 1000-8321, Japan. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of silicon dioxide as a carrier for flavors for use in animal feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of silicon dioxide as a carrier for flavors for use in animal feed and that the food additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order

12866.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

V. Objections and Hearing Requests

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in

the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. In § 573.940, add paragraphs (d) and (e) to read as follows:

§ 573.940 Silicon dioxide.

* * * * *

(d) It is used or intended for use in feed components, as a carrier as follows:

Feed Component	Limitations (percent)
Flavors	50

(e) To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

Dated: February 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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